VERMONT

Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
June 23, 2015

Board Members:
Present:

Clayton English, PharmD	Louise Rosales, NP	James Marmar, RPh
Janet Farina, RPh	Michael Biddle, PharmD	Joseph Lasek, MD, Chair

Absent:
Jaskanwar Batra, MD
Mark Pasanen, MD

Staff:

Michael Ouellette, RPh, GHS/Emdeon	Laureen Biczak,DO, GHS/Emdeon	Jason Pope, DVHA
Thomas Simpatico,MD, DVHA	Mary Beth Bizzari, RPh, DVHA	Laurie Pedlar, RPh, GHS/Emdeon
Nancy Hogue, PharmD, DVHA	Jennifer Egelhof, DVHA	Scott Strenio, MD, DVHA

Guests:

Rita Baglini, APS Health Care	Kristen Bruno-Doherty, Astrazeneca	Scott Williams, J&J
James Hayes, Abbvie	Thomas Currier, Purdue	Alicia Teitsma, AstraZeneca
Jai Persico, Otsuka	Kym McCafferty, AstraZeneca	Christine Dube, MedImmune
Brigit White, Avanir	David Halpin, AstraZeneca	James McGory, Avanir
Stew Hoover, UCB	Ron Iglesias, AstraZeneca	

Joseph Lasek, MD, Chair, called the meeting to order at 7:00 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:15 until 7:00 p.m.

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The May meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Updates: Nancy Hogue, PharmD, DVHA

- Welcomed the two new members of the DUR board, Louise Rosales,NP and Clayton English, PharmD.

4. Medical Director Update: Scott Strenio,MD, DVHA

- No update at this time

5. Follow-up Items from Previous Meetings: Mike Ouellette, RPh, GHS/Emdeon & Laureen Biczak, DO, GHS/Emdeon

a) 2015 Retro DUR Initiatives Schedule and Description

Mike Ouellette discussed the general outline for how RetroDUR interventions will be presented as well as the specific RetroDUR interventions that are planned for the rest of this year and early in 2016. The interventions chosen are the result of the input from the Committee over the last few meetings. The general process for completing RetroDUR interventions are as follows:

- Stage # 1: Detailed Retro DUR evaluation proposal is presented to the Committee for comments/revisions.
- Stage # 2: First presentation of results and determine next steps/potential interventions/determine need to repeat initiative in future if any; may finalize the intervention if no additional data cuts or questions required.
- Stage # 3: If needed, final presentation of data and determination of any needed follow up activities

At each meeting, we will be reviewing three different RetroDUR interventions, each at a different stage of development.

The RetroDUR initiatives to be undertaken in 2015 are:

- multiple benzodiazepine use concurrently
- amiodarone DDI
- hepatitis C DAA-adherence
- testosterone therapy-low level documented prior to therapy
- benzodiazepine use in the elderly
- asthma-controller use compared with ER visit and hospitalizations

Board Decision: None required

b) Data analysis of Amiodarone Laureen Biczak, DO GHS/Emdeon-Final Presentation

- Amiodarone is a potent anti-arrhythmic medication with a unique half-life of 26-107 days. Commonly relied upon tools such as DDI checkers at pharmacies,in EMR and with handheld devices, will not catch DDI due to drugs that were given in the past, so a RetroDUR initiative to determine whether this was a significant issue was undertaken where paid non-reversed pharmacy claims from 12/1/2014-6/1/2015 were used.
- Results: During this time period, there were 3 unique members who received a “high risk drug” within 120 days of oral amiodarone. In each case, the drug prescribed was azithromycin. One use was for 5 days of azithromycin concurrent with amiodarone therapy, one was 70 days after therapy with amiodarone and one instance was 49 days after the amiodarone therapy.None of the drug-drug interactions are ongoing. Dr.

Biczak concluded that the finding of 3 instances of this potentially life threatening drug-drug interaction occurrance within a 6 month period is significant.

Recommendation: Edits will be placed in the system to require a prior authorization for any high risk drugs that are prescribed concurrently with or within 120 days of an oral amiodarone prescription.

After a brief discussion, the Board recommended a look-back of 180 days for these edits.

Board Decision: The Board unanimously approved the above recommendation with the change to a 180 day look-back period.

6. Retro DUR/DUR:

a) Multiple Benzodiazepines Mike Ouellette, RPh. GHS/Emdeon-Initial Presentation

- This initiative was undertaken to ascertain the extent of multiple, concurrent benzodiazepine use in the Vermont Medicaid population. Paid, non-reversed pharmacy claims from 4/1/2014-12/31/2014 were used to look for instances where multiple benzodiazepines were utilized concurrently. Data was analyzed separately including and excluding clonazepam due to the common use of clonazepam for seizure control. During this period, there were 766 members on multiple benzodiazepines: 747 members on 2, 18 members on 3, and 1 member on 4. Excluding clonazepam, the most common combination was lorazepam and diazepam. After reviewing this data, a discussion was undertaken as to how best to further evaluate this utilization. Options presented included looking at the length of overlap to see if it was short term use suggesting tapering to change medication, looking at the number of different prescribers and looking at the member's diagnoses. The Board discussed the issues and determined that it would be most helpful to look at episodes with an overlap of at least 60 days and to determine the associated diagnoses and number of prescribers. The Board also recommended looking at concurrent utilization with the other sedative/hypnotics such as zolpidem.

Recommendation: GHS will narrow down the list of members by removing those that had an overlap period of less than 60 days and then bring back additional analysis on this group including the diagnosis data and the number of prescribers. This follow up will occur at the September DUR Board meeting.

Board Action: None required

b) Adherence to Hepatitis C Direct Acting Agents Laureen Biczak, DO, GHS/Emdeon

- The goal of this initiative will be to evaluate the adherence to these drugs over the previous 12 months. To analyze the adherence to treatment, for each patient, GHS will estimate and evaluate the following two most common measures of adherence: Medication Possession Ratio (MPR) and Proportion of Days Covered (PDC). Given the critical importance of adherence with these medications, patients will be considered "adherent" if they have an MPR and/or PDC of ≥ 90%. The more common criteria of ≥ 80% will be evaluated as well. This data will be presented at the September meeting.

Board Action: None required.

7. Clinical Update: Drug Reviews:

Abbreviated New Drug Reviews

a) Breo Ellipta®

- Breo Ellipta® has a new indication for the once-daily treatment of asthma in patients aged 18 years and older. There were numerous randomized, double-blind, controlled, confirmatory trials for the use of Breo Ellipta® in adults with asthma. Breo Ellipta® was compared to placebo and found to be significantly superior. Trial 5 was a 24 to 76 week exacerbation study that assessed if Breo Ellipta® 100/25 significantly decreased the risk of asthma exacerbation as measured by time to first asthma exacerbation vs fluticasone furoate 100mcg In another study it was compared with fluticasone/salmeterol. Statistically, the difference was not significant.

Recommendation: There is no evidence at this time to support that that Breo Ellipta® is more efficacious or safer than the currently available, more cost effective individual components (inhaled corticosteroids and Long-Acting Beta-Agonists (LABAs) or other combination products. Therefore, it is recommended that Breo Ellipta® remain non-preferred and require prior authorization and be available to the few patients who are unable to tolerate any preferred medications. Additionally, in the criteria section of the PDL the indication for asthma will be added.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

Additional Discussion: There is some cost benefit to keeping the Advair Diskus in the preferred position and moving the Advair HFA product to non-preferred. The State suggested that the board consider moving Advair HFA to non preferred on the PDL. The criteria for Advair HFA would state that it would need to submit a clinical reason why it is necessary to use the HFA versus the Diskus version of Advair. GHS will bring this back to the board for a vote in September.

b) Saphris®

- For treatment of schizophrenia in adults and for acute treatment of manic or mixed episodes associated with bipolar I disorder as monotherapy. The new indication is for children aged 10-17 years. Results of studies suggested that Saphris® was statistically superior to placebo.

Recommendation: It is recommended that Saphris® be placed in the non-preferred position on the PDL, require prior authorization and be available to the few patients who are unable to tolerate or who have failed on preferred medications. Criteria for Saphris® (asenapine): FDA maximum recommended dose= 20mg/day with quantity limit= 2 tabs/day. Saphris criteria: The patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization). OR medication is being requested for one of the target symptoms or patient diagnoses listed above in PDL AND patient has had a documented side effect, allergy or treatment failure with at least two preferred products after clinical criteria are met with products (typical or atypical antipsychotics), one of which is risperidone.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

Full New Drug Reviews: Mike Ouellette, RPh, GHS/Emdeon & Laureen Biczak, DO, GHS/Emdeon

a) Belsomra® (suvorexant)

- For the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance. This is a pregnancy category C medication. Dose adjustments are not required in those with renal or mild-to-moderate hepatic impairment. Several safety studies have been performed, including assessing the effects of Belsomra® on driving. Results suggested clinically meaningful impaired driving performance in some subjects. Therefore, the label contains warnings about next-day driving and other activities needing full-mental alertness.

Recommendation: It is recommended that Belsomra® be non-preferred, require prior authorization and be available to the few patients who are unable to tolerate or who have failed on preferred medications. Criteria for Belsomra® includes a trial of generic Zolpidem.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

b) Evzio® (Naloxone HCL)

- For the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression. Evzio® is intended for immediate administration as emergency therapy in settings where opioids may be present. If the desired response is not obtained after 2-3 minutes, another dose of Evzio® may then be administered. If there is still no response and additional doses are available, Evzio® may be given every 2-3 minutes until emergency medical assistance arrives.

Recommendation: It is recommended that Evzio® be non-preferred, require prior authorization and be available to the few patients who are unable to utilize the alternative delivery methods.

Public Comment: No public comment.

Board Decision: The board disscussed whether it was reasonable to expect someone unfamiliar with the nasal delivery method of naloxone, could use the naloxone with an nasal atomizer. Dr. Biczak added that she had done some research and found that naloxone is available in prefilled syringes, the atomizer is easily attached, and there are websites that offer very clear instructions about how to use this form of delivery. The Board unanimously approved the above recommendation.

c) Kitabis® (tobramycin solution)

- For the management of cystic fibrosis (CF) in adults and pediatric patients ≥6 years of age with *P aeruginosa*. There were two randomized, double-blind, placebo-controlled

24-week studies to assess the safety and efficacy of tobramycin inhalation solution in CF patients with *P aeruginosa*. Results suggested that there were significant improvements in pulmonary function in the tobramycin group versus placebo.

Recommendation: Kitabis® is a cost effective form of inhaled tobramycin co-packaged with a nebulizer and is recommended for preferred status after clinical criteria are met. *(Quantity Limit= 56 vials/56 days; maximum days' supply = 56 days; 2 vials/day for 28 days, then 28 days off)*

In addition, based on utilization patterns, it was recommended that TOBI Podhaler move to preferred status and that the criteria be changed to require a diagnosis of cystic fibrosis and a trial of another form of tobramycin inhalation therapy.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) Onexton® (clindamycin phosphate & benzoyl peroxide gel)

- For the topical treatment of acne vulgaris in those ≥12 years of age. This is a pregnancy category C medication. Wash face with mild soap and warm water prior to application of gel. Apply pea-size amount of gel to face once daily. There was no data found that Onexton® was safer or more effective than alternative, most cost effective preferred agents.

Recommendation: It is recommended that Onexton® be non-preferred, require prior authorization and be available to the few patients who are unable to tolerate or who have failed on preferred medications. It is also recommended that sodium sulfacetamide and sulfur products be moved to the non-preferred position on the PDL.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

e) Soolantra® (ivermectin)

- Indicated for the treatment of the inflammatory lesions of rosacea. This is a pregnancy category C medication. The most frequently reported adverse events reported were skin burning sensation and skin irritation. Soolantra® cream was an effective treatment compared with placebo, and one study suggested that it may be superior to metronidazole 0.75% cream when used for the treatment of rosacea. Long-term studies of up to 40 weeks support its safety.

Recommendation: It is recommended that Soolantra® be non-preferred, require prior authorization and be available to the few patients who are unable to tolerate any or who have failed on preferred medications. Also in reviewing this class, we recommend moving Finacea gel to preferred as it is now a cost effective alternative.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

f) Spiriva® Respimat (tiotropium bromide)

- For the long-term, once-daily maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema AND to reduce exacerbations in COPD patients. There was no evidence presented of improved efficacy or tolerability of this device versus the Spiriva® Handihaler.

Recommendation: It is recommended that Spiriva® Respimat be non-preferred, require prior authorization and be available to the few patients who are unable to tolerate or who have failed on preferred medications. Criteria will state: Spiriva Respimat: patient has a diagnosis of COPD and a compelling clinical reason why they cannot use the Spiriva® Handihaler.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

8. Therapeutic Drug Classes- Periodic Review: Mike Ouellette, RPh, GHS/Emdeon and Laureen Biczak, DO, GHS/Emdeon

a) Antihistamines, Second Generations

- No new drugs in this category.
- A 2014 Cochrane Review by Sharma et al[65] included 34 randomized controlled trials to assess the efficacy of H1-antihistamines for the treatment of chronic spontaneous urticaria. The authors concluded that due to the quality of the evidence, impacted by small sample sizes and small number of studies, there was not one H1-antihistamine that stood out as most effective. A 2015 network meta-analysis by Xiao et al[66] included 13 randomized controlled trials to assess the effectiveness of 4 allergic rhinitis medications for reducing functional problems in patients, per the rhinoconjunctivitis quality of life questionnaire scores. The medications included loratadine, cetirizine, desloratadine, and montelukast. The authors concluded that the results of the network meta-analysis suggest cetirizine is the most effective treatment for AR compared with loratadine, montelukast, and desloratadine.

Recommendation: Keep current criteria, drugs that are no longer available to be removed

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

b) Intranasal Agents

- No new drugs in this category.
- In 2015, the American Academy of Otolaryngology- Head and Neck Surgery (AAO-HNS) published clinical practice guidelines for allergic rhinitis (AR)[106] and it recommended that topical steroids be used for AR when quality of life is affected. There was also a strong recommendation for using oral second-generation antihistamines for AR for the chief complaints of sneezing and itching, and if inadequate response is seen with monotherapy, combination therapy may be offered. In addition, another reference source cited suggested that, "in those with persistent or moderate to severe symptoms despite treatment, the

addition of a topical second-generation antihistamine spray should be used "...in preference to other agents.

Recommendation: Keep current criteria, drugs that are no longer available to be removed

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) Genital Warts and Actinic Keratosis Agents

- No new drugs in this category.
- A 2014 Cochrane Review by Grillo-Ardila et al[42] included 10 randomized controlled trials (N=1734) to assess the safety and efficacy of imiquimod when used for the treatment of anogenital warts in non-immunocompromised adults. Low quality evidence suggests that imiquimod and podophyllotoxin or podophyllin have similar benefits but imiquimod has fewer systemic adverse reactions.
- A 2005 meta-analysis by Gupta et al[55] included 10 studies to assess the efficacy of imiquimod 5% cream as compared to 5-fluorouracil when used for the treatment of actinic keratosis (AK). The authors concluded that both treatments are effective for the treatment of AK. but that imiquimod may be more effective than 5-fluorouracil.

Recommendation: No changes recommended to the category or criteria, however it was suggested that Efudex® move to the preferred position and generic fluorouracil 5% to non-preferred due to cost considerations.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) Idiopathic Pulmonary Fibrosis Agents

- No clinically significant changes

Recommendation: Keep current category and criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

e) Inflammatory Bowel Agents (Oral & Rectal Products)

- Uceris® Rectal Foam, New drug in this category
- The American College of Gastroenterology (ACG) has clinical guidelines that recommend specific medications based upon goals of treatment. The current PDL has a reasonable variety of medications available in various forms.

Recommendation: It is recommended that Uceris ER Tab® be made non-preferred and the Uceris Rectal Foam® be preferred. It is also recommended that due to a significant cost differential, for new starts, the Pentasa ER 250mg be preferred and Pentasa ER 500mg be non-preferred. Current users will be grandfathered.

Public Comment: No public comment.

Board Decision: The Board discussed the question of the pill burden with the various mesalamine products in this class and concluded that there were several options with low pill burdens that were preferred. The Board unanimously approved the above recommendation.

f) Otic Anti-Infectives

- The American Academy of Otolaryngology Head and Neck Surgery Foundation updated their guideline for otitis externa in 2014, and recommended that systemic antibiotics should not be prescribed "...as initial therapy for diffuse, uncomplicated AOE unless there is extension outside the ear canal or the presence of specific host factors that would indicated a need for systemic therapy." Topical preparations should be prescribed for initial therapy of diffuse, uncomplicated AOE. The guidelines also indicate that as there is a lack of difference in efficacy amongst the topical antimicrobial and steroid products and therefore patient preference, clinician experience, cost, adherence to therapy, and adverse events should all be considered when selecting therapy.

Recommendation: It is recommended that Cipro-HC susp (ciprofloxacin 0.2%/HC 1%) and Ciprodex® be preferred and ofloxacin 0.3% Soln be made non-preferred as it is no longer a cost-effective choice.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

g) Pseudobulbar Affect Agents

- The only drug included in this therapeutic class review is dextromethorphan hydrobromide/quinidine sulfate (Nuedexta®). The FDA labeling for this product recently changed clarifying that the indication was for Pseudobulbar Affect disorder (PBA) due to any neurologic condition. However, it was pointed out that there are not published peer-reveiwed studies on the efficacy for this beyond use in multiple sclerosis and ALS. Since the drug is not effective 100% of the time, it is reasonable to require baseline and follow up testing to measure if the drug is being effective.

Recommendation: Clinical criteria for Nuedexta : The patient must have a diagnosis of pseudobulbar affect (PBA) secondary to a neurological condition **AND** the patient has had a trial and therapy failure at a therapeutic dose with a tricyclic antidepressant (TCA) or an SSRI **AND** the patient has documentation of a current EKG (within the past 3 months) without QT prolongation **AND** initial authorizations will be approved for 6 months with a baseline Center for Neurologic Studies Lability Scale (CNS-LS) questionnaire **AND** subsequent prior authorizations will be considered at 6 month intervals with documented efficacy as seen in an improvement in the CNS-LS questionnaire.

Public Comment: James McGory, Avanir: Highlighted some of the attributes of Nuedexta®

Board Decision: The Board unanimously approved the above recommendations.

9. New managed Therapeutic Drug Classes

a) Selected Contraceptive Products

- There are many clinical studies showing that the various contraceptives are effective, however, given the sheer number of effective products available, it is recommended to consider having a number of cost-effective products available in each of the categories. As an overview, the products are broken down into the following groups: monophasic agents, biphasic agents, triphasic agents, extended cycle agents, progestin only contraceptives, non oral contraceptives, and emergency contraceptives. The study suggested that the extended cycle formulations may be more favorable with regard to headaches, bloating, and menstrual pain. The recommendation of most studies and guidelines is to start with a monophasic agents for most patients.

Recommendation: Monophasic Agents: Due to the extensive list of monophasic products, it is not practical to list all the preferred products. Therefore, any monophasic oral contraceptive not listed on the PDL as non-preferred, is considered preferred. For biphasic agents, the only non-preferred product will be Mircette. The criteria recommended for non-preferred drugs includes a trial of at least 3 preferred products including the preferred version of the specific non-preferred agent being requested.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

10. Review of Newly-Developed/Revised Clinical Coverage Criteria and/or Preferred Products

- None at this time.

11. General Announcements Mike Ouellette, RPh, GHS/Emdeon

- Selected FDA Safety Alerts
  - FDA Drug Safety Communication: FDA warns that SGLT2 inhibitors for diabetes may result in a serious condition causing too much acid in the blood http://www.fda.gov/Drugs/DrugSafety/ucm446845.htm
    - No action required.

13. Adjourn: Meeting adjourned at 8:16 p.m.